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PATENT

Applicant: **Bobo, Jr.**
Serial No.: **10/021,132**
Filed: **10/29/2001**
Title: **METHOD AND APPARATUS FOR
PROVIDING MEDICAMENT TO
TISSUE**
Group Art Unit: **3732**
Atty Docket No.: **15646-42**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RESPONSE TO NOTICE OF INCOMPLETE REPLY (NONPROVISIONAL)

Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Notice of Incomplete Reply (Nonprovisional) (copy enclosed) mailed June 3, 2002, Applicant responds as follows.

Please amend the Abstract as follows:

METHOD AND APPARATUS FOR PROVIDING MEDICAMENT TO TISSUE

ABSTRACT


A system for delivering medicaments to tissue including a delivery member and an optical fiber formed together into a unitary structure. The optical fiber has an inlet attached to a laser energy source and an outlet for emitting laser energy. The delivery member has an inlet attached to a medicament source and an outlet for injecting medicament. A handpiece is adapted to receive the ablating and injecting device in a controlled and movable relationship and may include at least one tissue stabilizing member thereon. In use, the distal end of the handpiece is placed against tissue to be ablated. The optical fiber is advanced into the tissue while emitting laser energy thereby ablating the tissue and forming a channel therein. During retraction, medicament may be injected into the channel or into the tissue surrounding the channel.

It is believed that no fees are due in connection with this response. If any fees are due, the Commissioner is authorized to charge Deposit Account 50-1901.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changed made.**" A clean copy of the Abstract on a separate page is also included.

Respectfully submitted,

June 14, 2002


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METHOD AND APPARATUS FOR PROVIDING MEDICAMENT TO TISSUE

ABSTRACT

A system for delivering medicaments to tissue include[es]ing [a tissue-removal and medicament-delivery device. The device includes] a delivery member and an optical fiber formed together into a unitary structure[by cladding]. The optical fiber has an inlet [for receiving laser energy from] attached to a laser energy source and an outlet for emitting laser energy. The delivery member has an inlet[for receiving medicament from] attached to a medicament source and an outlet for injecting medicament. A handpiece is adapted to receive the ablating and injecting device in a controlled and movable relationship [. The distal end of the handpiece disposes] and may include at least one tissue stabilizing member thereon. [For example, in one embodiment the tissue stabilizing member comprises deployable needles or barbs which engage the tissue positioned proximate thereto, thereby securely positioning the device. In another embodiment, the tissue stabilizer comprises vacuum ports in communication with an external vacuum source. Alternatively, the tissue stabilizer may further comprise at least one inflatable balloon which engages the tissue disposed proximate thereto.] In use, [a] the distal end of the handpiece is placed against tissue to be ablated. The [ablating and injecting device] optical fiber is advanced [beyond the distal end of the handpiece and] into the tissue while emitting laser energy [from the optical fiber. The emitted laser energy] thereby ablat[es]ing the tissue [as the optical fiber advances. The ablating and injecting device handpiece is then retracted from the tissue, thereby resulting in] and forming a channel[formed in the tissue] therein. [While the device retracts,] During retraction, medicament [is] may be injected [from the delivery member] into the channel [, thereby providing a plug within the channel. Alternatively, medicament may be injected] or into the tissue surrounding the channel, [by delivering the medicament into the tissue surrounding the channel] opening or delivering it directly into the channel wall. In an additional embodiment, sealing balloons may be used to

increase the retention of the medicament within the tissue and prevent medicament washout. The medicament may include growth factor combined with a cellular matrix which enhances angiogenesis in the tissue or may include a gene that encodes for said growth factor, or any other therapeutic agent or gene therapy agent that promotes angiogenesis or any therapeutic agent for the treatment of cardiovascular disease. The medicament delivery system is particularly useful in cardiac applications for performing transmyocardial revascularization (TMR) in ischemic myocardium and promoting endothelial cell growth within the myocardium].

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